

Expert Panel Backs 'Right to Volunteer' as Research Subject

Medical Tribune Report

WASHINGTON—Should soldiers, prisoners, and the poor be used in medical experiments, and if so, under what conditions?

A panel of legal and medical experts discussed these questions at a forum of the National Academy of Sciences on "Experiments and Research with Humans: Values in Conflict." While the range of opinions expressed was wide, the panelists managed—with one exception—to find some common ground of agreement on principle.

"Prisons are inherently coercive," said Alvin J. Bronstein, Executive Director-Counsel, National Prison Project, American Civil Liberties Union Foundation, "and therefore experimen-

tation on prisoner subjects should not be permitted." Mr. Bronstein's criteria were drawn from the Nuremberg code, which stipulates that medical experiments on humans can only be legally carried out with the subject's "voluntary consent," and such consent can only be given by a person "so situated as to be able to exercise free power of choice." Overt and subtle pressures on prisoners to take part in research experiments disqualifies them from being true volunteers, in Mr. Bronstein's view.

He was the only speaker who would exclude a whole class of people from participating as subjects in experiments—or, in the words of Dr. Albert B. Sabin, Distinguished Research Profes-

sor of Biomedicine, Medical University of South Carolina, "deprive them of the right to volunteer." Dr. Sabin and the other panelists, Dr. William N. Hubbard, Jr., President, the Upjohn Company, and Dr. Jay Katz, Adjunct Professor of Law and Psychiatry, Yale Law School, weighed the social risks and benefits of human experiments, and tried to define standards of "informed consent."

Malaria, Polio Drugs Cited

Dr. Sabin asserted that some of the most important preventive and therapeutic drugs in current use, including those against malaria and polio, could not have been developed without research on volunteers in the uniquely

suitable environments found in the Armed Forces and prisons, which afford "conditions of strict isolation and convenient ongoing observation." The need persists for similar studies on other diseases as yet incompletely understood he said, such as viral hepatitis.

Dr. Sabin recalled his own experiences with volunteers over a period of more than thirty years, during which he investigated Japanese encephalitis, Phlebotomus fever, and the polio-virus vaccines. He said that provided the volunteer was fully informed of the possible personal risks and societal benefits of what he was getting into, such experiments were humane, and in fact appealed to the volunteers' best sense of altruism.

Dr. Hubbard agreed on the special value of studies conducted among pri-

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Wednesday, April 16, 1975

Polish Venereologists Said To Show Punishing Attitude

By JAMES MAGEE
Medical Tribune World Service

GENEVA—Polish physicians who specialize in venereal disease take a stern view of their patients, according to a survey of their attitudes.

Prison sentences, compulsory work camps, fines, police surveillance, and other penalties were among proposals put forward to deal with the problem, sociologist Jan Kelus, of Warsaw Medical Academy Institute of Venereology, told a W.H.O. meeting here on health education in the control of sexually transmitted diseases.

Of 144 VD specialists who replied to a questionnaire, nearly 68 said that a person with VD who avoided medical help should be sent to jail. Similar punishment was suggested for prostitution, homosexuality, and infecting another person with VD.

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**EDITORIAL
GUIDELINES**

... brief summaries of editorials or comments in current medical and scientific journals.

Risk Factor Reappraisal

"Within a decade we should learn the results of National Heart and Lung Institute studies of reducing lipids in certain lipid disorders and of controlling hypertension; we should also have data on the promising possibility that control of a combination of three major risk factors may affect the course of coronary disease. If risk factor interventions prove successful, and if these measures were then applied to the entire population it would appear that at best only about 5 to 20 percent of cases could be controlled. If intervention trials were implemented to control risk in the genetically prone high-risk offspring in infancy, possible benefits would not be learned until that population reached the age of clinical manifestations, 50 to 65 years later.

"These considerations suggest an urgent need for new fundamental research and reappraisal of existing experimental and clinical studies, including national population research. Perhaps future studies should investigate in man immunologic and other factors that cause accelerated obstruction of the transplanted veins used in coronary or femoral bypass surgery, and galloping atherosclerosis in the transplanted heart...

"Imaginative investigators might well look for other likely causes of arteriosclerosis...

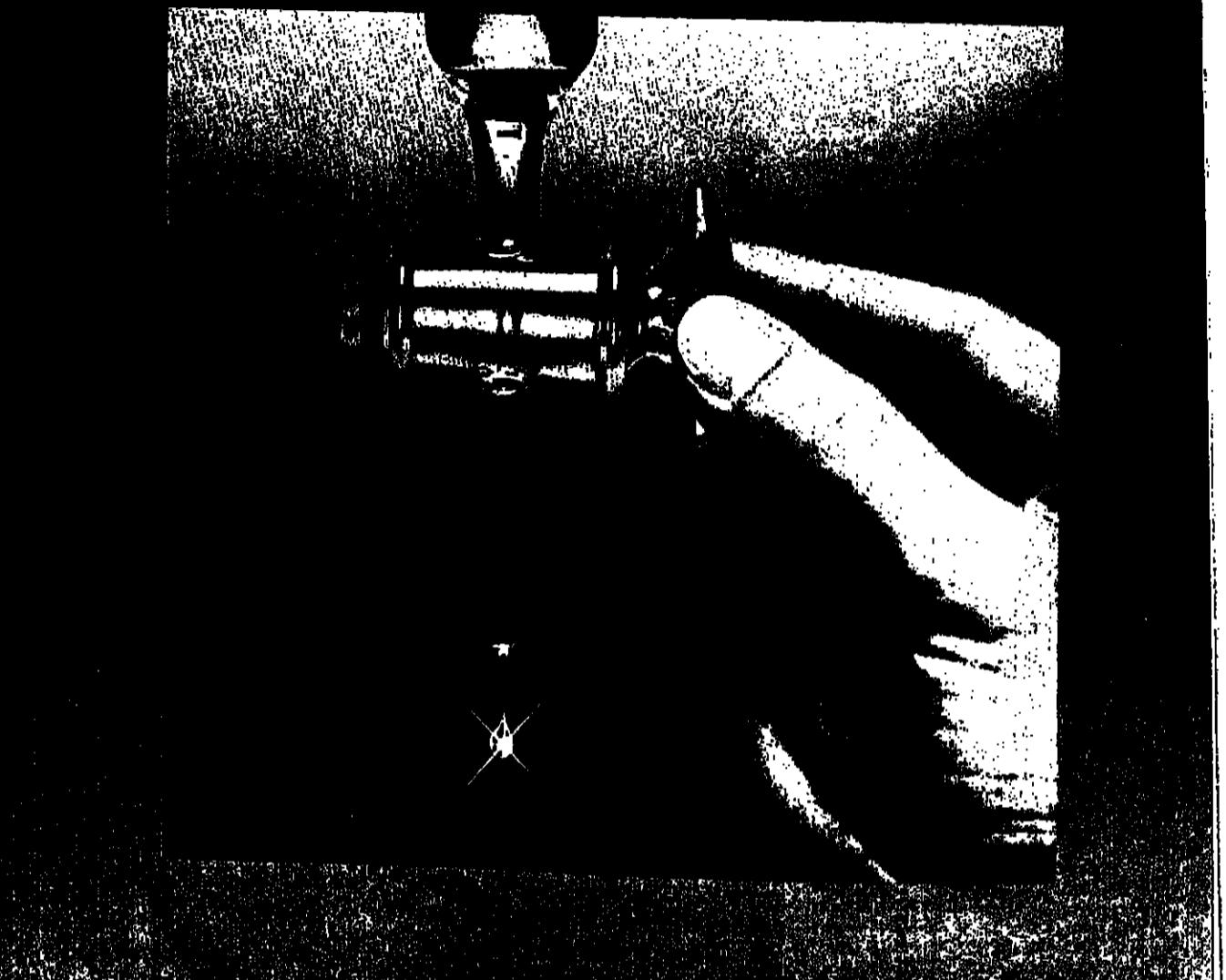
"... It was Einstein's famous equation $E = mc^2$ that provided a major step toward the development of nuclear energy. As yet, we do not appear to possess a formula for the basic genesis of the arteriosclerotic lesion and its prevention because we do not understand the basic underlying mechanisms or how various risk factors influence the progress of the lesion to bring about clinical disease. This lack of knowledge makes it difficult to provide rational programs for prevention and treatment...

"If the multiple risk factor trials fail to prevent the progress of arteriosclerosis, health planners may be reduced to a state of scientific bankruptcy. In planning the defense of a country, the military plan for all future eventualities, including possible failure; the scientific community should also have plans under way in case multiple risk factor trials fail...

"It appears that our nation's overconfidence in present risk factor concepts is impeding development of other promising preventive approaches. Because it will take years to dislocate and relocate the human resources for a new major multidisciplinary attack on the problem of arteriosclerosis, we plead that our Congress provide the highest priority of funding to encourage a more massive research attack now... 'Where are the alternate plans for defense against our nation's biggest killer?' (Editorial, Eliot Corday, M.D., F.A.C.C. and Stephen Richard Corday, M.D. Am. J. Cardiol. 35:330, Feb., 1975)

Esimil® begins with a thiazide

guanethidine monosulfate 10 mg
hydrochlorothiazide 25 mg


Esimil®

guanethidine monosulfate 10 mg
hydrochlorothiazide 25 mg

INDICATIONS
Hypertension. (See box warning.)

WARNING
This fixed combination drug is not indicated for initial therapy of hypertension. Hypertension requires therapy titrated to the individual. It represents the dosage of each component. It may be more convenient in patient management. The treatment of hypertension is not absolute, but must be reevaluated as conditions in each patient warrant.

CONTRAINDICATIONS
Guanethidine Known or suspected pheochromocytoma. Frank congestive heart failure not due to hypertension; use of MAO inhibitors.

Hydrochlorothiazide Anuria; hypersensitivity to thiazide or thiazide-derived drugs. The pregnant woman with or without normal renal function should be used with extreme caution in hydrochlorothiazide because of the potential for congenital anomalies and the greater propensity for cardiac arrhythmias.

Any hypotensive agent, potent drugs and can lead to disturbing and serious side effects. Physicians should be familiar with all drugs and combinations before prescribing, and patients should be warned not to deviate from instructions.

Guanethidine

Warn patients about the potential hazard of orthostatic hypotension which occurs frequently and is most marked in the morning or evening. To prevent fainting, warn patients to sit or lie down on onset of dizziness or weakness, which may be particularly apt to occur with postural changes.

The potential occurrence of these symptoms requires caution in the elderly, children, and young patients to avoid sudden or prolonged standing or exercise before taking the drug.

Concurrent use with rauwolfia derivatives may cause excessive postural hypotension, bradycardia, and mental depression.

If surgery is indicated, withdraw therapy 2 weeks prior to collapse and cardiac arrest. The possibility of vascular emergency surgery is indicated, especially if reduced blood and have oxygen, atropine, in vasodilators, etc. If surgery is ready for immediate use to treat vascular crisis, the physician should be used with extreme caution in hydrochlorothiazide because of the potential for hypotension and the greater propensity for cardiac arrhythmias.

Use with caution in severe renal disease. In patients with renal disease, thiazides may precipitate azotemia. The diuretic effects of the drug may develop in patients with impaired renal function.

The drug should be used with caution in patients with impaired hepatic function or progressive liver disease, since minor alterations of fluid

and electrolyte imbalance may precipitate hepatic coma.

Thiazides may be additive or potentiate the effects of other antihypertensive drugs. Potentiation may occur by hot weather, alcohol, or exercise. To prevent fainting, warn patients to sit or lie down on onset of dizziness or weakness, which may be particularly apt to occur with postural changes.

The possibility of exacerbation or activation of systemic lupus erythematosus has been reported.

Usage in Pregnancy Guanethidine: The safety of guanethidine for use in pregnancy has not been established; therefore, this drug should be used in pregnant patients only when, in the judgment of the physician, its use is deemed essential to the well-being of the patient.

Hydrochlorothiazide: Usage of thiazides in women of childbearing age requires that the potential benefits of the drug be weighed against the possible hazards to the fetus. The following include fetal anomalies—congenital anomalies, thromboembolic, and possibly other adverse reactions which have occurred in the adult.

Nursing Mothers It is not known if the placental barrier and appear in cord blood and breast milk.

PRECAUTIONS Guanethidine: The effects of guanethidine are cumulative over long periods. Initial dose should be small and increased gradually in small increments. Use very cautiously in hypertension with renal disease. Hypertension, edema, or rising BUN levels; coronary disease with insufficiency or recent myocardial infarction; cerebral vascular disease, especially with emboli; and congestive heart failure. Do not give guanethidine to patients with known cardiac failure except with extreme caution.

In incipient cardiac decompensation weight gain may be averted by the administration of a diuretic. However, both digitalis and guanethidine slow the heart rate.

Hydrochlorothiazide: Hypertension, nausea, vomiting, cramps, diarrhea, constipation, headache (intrahepatic cholestasis), gout, rash, dizziness, vertigo, paresthesias, tachypnea, tinnitus, Stevens-Johnson syndrome, and other hypersensitivity reactions. Hematologic, hepatotoxic, and other adverse reactions—orthostatic hypotension may occur and may be potentialized by alcohol, barbiturates, or narcotics.

Other—hyperglycemia, glycosuria, hyperuricemia, muscle spasm, hypotension, hypotension, hypoglycemia, and other adverse reactions.

When adverse reactions are moderate or severe, reduce dosage or withdraw therapy.

DOSEAGE As determined by individual titration (see box warning).

If nitrogen retention indicates onset of progressive renal impairment, consider withholding or discontinuing diuretic therapy.

Thiazides may decrease serum PBI levels without signs of thyroid disturbance.

ADVERSE REACTIONS

Guanethidine: Frequent reactions due to sympathetic blockade—dizziness, weakness, tinnitus, syncope. Frequent—dryness of eyes, tachycardia, increase in bowel movements, diarrhea (may be severe and necessitate discontinuation of the drug).

Other common reactions—orthostatic hypotension, edema, constipation, metabolic effects of hypokalemia especially with reference to myocardial activity.

Any cardiac deficit is generally mild and usually does not require specific treatment except under extraordinary circumstances (e.g., in shock, edema or renal disease). Dilutional hypoproteinemia may occur in edematous patients in hot weather.

Thiazides therapy is water restriction rather than administration of salt, except in rare instances when the hypoproteinemia is life-threatening.

...because it is the standard initial therapy—the logical foundation upon which to build. And we picked hydrochlorothiazide, the most widely prescribed diuretic-antihypertensive, which we

...added to perhaps the most effective antihypertensive available, guanethidine...

to create a logical team of therapeutic activities

...for controlling moderate to severe hypertension.

to provide an alternative therapy

...which often controls hypertension in patients not responding to sedatives, diuretics, rauwolfia-thiazides, or other centrally acting inhibitors alone or in combination.

to avoid exacerbating the problem of mental depression

...because Esimil contains no reserpine.

to encourage patient compliance

...because Esimil usually works in once-a-day dosage.

Like all antihypertensives, Esimil should be given with caution in the presence of severe coronary insufficiency or recent myocardial infarction.

Dissatisfied with your present antihypertensive therapy? Why don't you start with the same effective components we did, and when your carefully titrated dosage matches ours—switch to Esimil.

titrate to
Esimil®
guanethidine monosulfate 10 mg
hydrochlorothiazide 25 mg

'Right to Volunteer' For Research Gets Panelists' Support

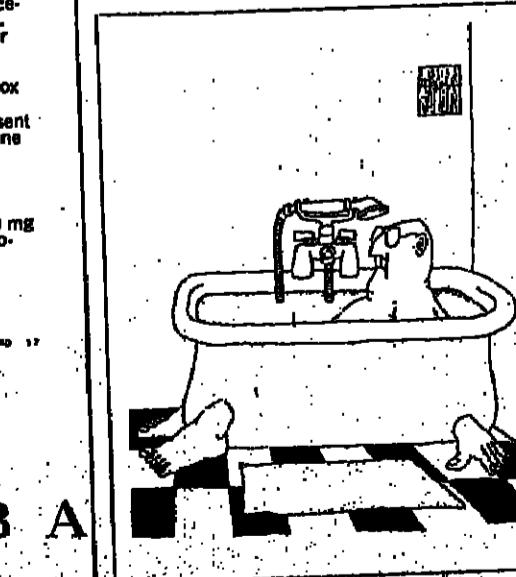
Continued from page 2
oners and soldiers, but stressed the importance of guidelines to reduce to a minimum any element of coercion. In the Michigan prison system where he has been involved in the testing of drugs for fifteen years, Dr. Hubbard said there is an elaborate procedure of full explanation to all volunteers of dangers, discomforts and civil rights. Moreover, volunteers are not solicited, and they are expressly told that their participation will have no bearing on parole eligibility. All drug research programs must be unanimously approved by a Protection Committee comprising two biomedical scientists, three physicians, and two lawyers, one of whom must be associated with prisoner advocacy. The prisoner has the right to withdraw from the study at any time.

According to Dr. Hubbard, since 1964, 12,000 Michigan inmates have participated in drug research studies, with one death from "stroke" of a subject serving as a placebo control, and nine illnesses without sequelae.

Full Disclosure Stressed

Dr. Katz, focusing on problems of experiments on the poor, also emphasized the importance of "full, total disclosure" if such experiments are to be humane and truly progressive. While not questioning the need for controlled clinical trials, he cited various abuses by investigators, who had lost sight of their subjects as fellow human beings, as in the Tuskegee syphilis studies, which had also been brought to the panel's attention by Mr. Bronstein. However, Dr. Katz warned against the wholesale exclusion of any group from voluntary participation—such exclusion, he said, stemmed from the same "stereotypical" prejudices that had led to "degrading" abuses.

"It is equally demeaning to assert that persons' consent should be rejected because, if they were wiser or more rational, they would have made different decisions, as it is to assert that their consent should not be trusted because, if they only were richer, they would have chosen differently," Dr. Katz said. "Ultimately we must bow to the best decisions persons can make as they are situated."



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5/24/75

Hot Price Label Fumes Implicated in Meatwrapper's Asthma

Medical Tribune Report

SAN DIEGO, CALIF.—Fumes from hot meat price labels and not the polyvinyl chloride (PVC) in plastic wrappings have been implicated as the primary culprit in "meatwrapper's asthma," an occupational disease first reported about two years ago.

Within 30 seconds to twenty minutes after exposure to fumes produced when meat package labels were heated on a commercial labelling machine, nine of 13 meat-wrapping personnel developed immediate severe bronchoconstriction in a study, carried out under simulated working conditions, by Dr. Rudi Andrasch and his colleagues at the University of Oregon Health Science Center.

Eight workers developed paroxysmal cough; and deep cyanosis, tachycardia, diaphoresis, and dizziness were observed in five others. Dr. Andrasch told the 31st annual meeting of the American Academy of Allergy here. In addition, other workers in the study reported shakiness, severe burning in the nose and throat, headache, nausea, muscle ache, rhinorrhea, weakness, vomiting and hoarseness, he said.

Response to Medication

"Three patients showed an excellent response to subcutaneous epinephrine, four patients required intravenous aminophylline in addition, and two patients continued to manifest severe bronchospasm requiring additional treatment with IPPB and phenylephrine with isoproterenol.

"This study indicates that the fumes of thermosactivated price labels are the principal culprit of meat-wrapper asthma. Paroxysmal cough and acute bronchospasm developed more frequently after shorter periods of exposure [than to PVC fumes] and tended to be much more severe.

"Dryness and burning of the mucous membranes, severe headache, extreme irritability and nausea were frequent

associated symptoms. Fumes of polyvinyl chloride soft wrap resins are also mucous membrane and respiratory irritants which may in a smaller group of meatwrappers cause moderate to severe reactive airway disease," Dr. Andrasch explained.

Although the fumes from the heated meat labels have still not been chemically identified, the adhesive backings are known to contain miscellaneous elastomers, thermoplastic copolymers, styrene butadiene copolymers, styrene acrylonitrile copolymers, polyphenylene oxides, polysulfones and phthalic acid plasticizers, the Oregon researcher said. Fumes produced when PVC wrappings are sliced by hot wire cutters, include carbon monoxide, carbon dioxide, hydrochloric acid, and various plasticizers, as well as hydrocarbons and chlorinated compounds.

Syndrome a Complex Response

"Even though price label fume intolerance accounts for most of the respiratory symptoms, the entire spectrum of the meat wrapper's syndrome has to be interpreted as a complex response to both PVC and price label fume exposure," Dr. Andrasch emphasized.

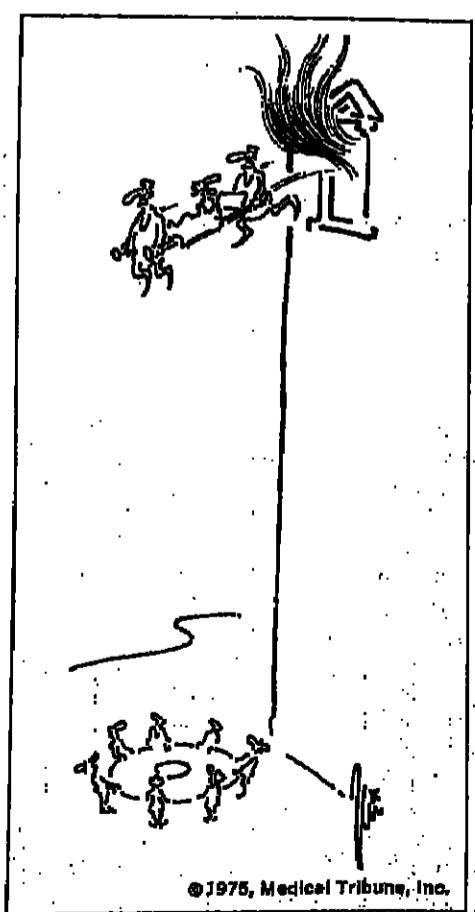
The Oregon study, supported by the local Meat Cutter's Union, followed a survey of 67 meatwrappers in the Portland area. Of those who responded, 57 per cent reported "moderate to severe respiratory symptoms," while a smaller number complained of head-

ache, sore throat, stomach cramps, and nasal congestion among other symptoms. In some cases, the attacks began three to four hours after the employee commenced work, but others began to have difficulties within the first ten to fifteen minutes on the job.

At the present time, two court cases involving meat wrapper's asthma are pending, two in Portland and one in Kentucky, Dr. Andrasch said, noting that from 25,000 to 50,000 meatwrappers, meat cutters, and supervisory personnel are exposed to fumes from PVC or label adhesives in their work.

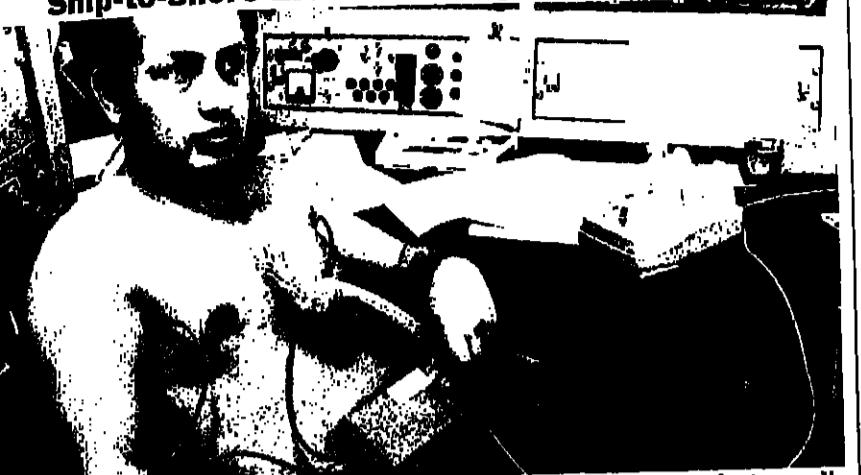
New film cutting machines seem to be reducing the PVC hazard at this time, Dr. Andrasch concluded, suggesting that the hazards from meat label fumes could also be minimized through the expanded use of recently developed automatic labelling machines.

after taking a potent analgesic 360 times in a week



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Ship-to-Shore Electrocardiography Initiated



Zim company, the Israeli shipping line, has installed ship-to-shore electrocardiography on one of its vessels in what is believed to be the first trial of its kind. The machine is connected by radiotelephone to a monitor at Rambam Hospital in Haifa. The initial test, carried out when the ship was 600 miles off Haifa, was reported to have produced surprisingly clear results.

California Acupuncture Body With Few MDs Expected Soon

By EDWARD GROSSMAN
Medical Tribune Staff

SACRAMENTO, CALIF.—Despite opposition from some physicians, it seems likely that California will soon have a law creating an Acupuncture Advisory Board, comprised of two M.D.s and five "traditional" acupuncturists, which would be empowered to issue certificates of qualification to practice acupuncture as "a healing art."

Bill number 86, introduced by Senator George Moscone, D-San Francisco, was recently passed by a vote of 22-1 in the State Senate. John Jervis, aide to Sen. Moscone, told MEDICAL TRIBUNE that he expects smooth sail-

ing in the Assembly as well. The bill would then have to be signed by Gov. Edmund Brown, Jr., and would take effect as law Jan. 1, 1976.

A similar bill was approved overwhelmingly by both houses of the legislature last September, but was vetoed by former Gov. Reagan, who said that acupuncture was still in the research stage.

Restriction Flouted

Under present California law, only licensed professionals (M.D.s, D.D.S.s, and chiropractors) are permitted to puncture the skin for therapeutic purposes. However, many non-licensed herbalists and "doctors of Chinese Medicine" have been practicing openly, with only sporadic prosecution and, infrequently, the imposition of small fines.

The Moscone measure would make it a misdemeanor to practice acupuncture or "hold oneself out as an acupuncturist" without a certificate issued by the new Advisory Board. Furthermore, acupuncture could not be performed without "prior diagnosis or referral" from a physician.

The Advisory Board is to be under the jurisdiction of the state Board of Medical Examiners and its members are to be appointed by the Governor. It will be charged with establishing standards, tests, and other requirements, and will pass on the applications of all licensure candidates, with acupuncturists having more than five years experience receiving priority consideration.

The law would not affect the right of physicians and dentists to practice acupuncture.

Several California physicians who find fault with the Moscone proposal concede that it is virtually assured of passage. Their main objection concerns the composition of the Advisory Board.

Many Poorly Trained

"There are many so-called 'traditional' acupuncturists, trained in Hong Kong and elsewhere, who are skilled and conscientious," Dr. Jane F. Lee, a San Francisco general practitioner, told MEDICAL TRIBUNE. "But there are also many others who have been poorly trained, and have little knowledge of physiology, pathology and anatomy. I'm worried that with the drastic imbalance between M.D.s and 'traditionals' on the Board, there might be wholesale certification of unqualified practitioners. I'd like to see a more balanced approach."

Dr. Lee is a member of the Acupuncture Committee of the California Medical Association, which so far has not taken a position on the bill.

Her view is shared by Dr. George Wong, Jr., a family practitioner in Long Beach, who, like Dr. Lee, has extensive training in acupuncture and uses it as an "adjunct mode" in his practice. Dr. Wong is Chairman of the Acupuncture Research Institute Alumini Association, a non-profit organization of physicians interested in acu-

Continued on page 23

in chronic pain
of moderate to severe intensity
Talwin® 50 mg. Tablets
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Overdosage Manifestations. Clinical experience with Talwin overdosage has been insufficient to define the signs of this condition.
Treatment. Oxygen, intravenous fluids, vasopressors, and other supportive measures should be employed as indicated. Assisted or controlled ventilation should also be considered, although metocarbamol and levorphanol are not effective antidotes for respiratory depression due to overdosage or unopposed analgesia. Naloxone (Narcan, available through Endo Laboratories) is a specific and effective antagonist.
Talwin is not subject to narcotic control.
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*This drug has been evaluated as possibly effective for this indication. See brief prescribing information.

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TABLETS

INDICATION
Based on a review of this drug by the National Academy of Sciences-National Research Council and/or other information, FDA has classified the indication as follows:
"Possibly" effective: Mild depression. Final classification of the less-than-effective indications requires further investigation.

CONTRAINDICATIONS
Marked anxiety, tension, and agitation, since Ritalin may aggravate these symptoms. Also contraindicated in patients known to be hypersensitive to the drug and in patients with glaucoma. While Ritalin should not be used in children under six years, since safety and efficacy in this age group have not been established.

Sufficient data on safety and efficacy of long-term use of Ritalin in children with minimal-brain dysfunction has not yet been established. Although a causal relationship has not been established, stupor, coma, fits, fits of giddiness and/or fits of fits (epilepsy) have been reported with long-term use of stimulants in children. Therefore, children requiring long-term therapy should be carefully monitored.

Ritalin should not be used for severe depression of either exogenous or endogenous origin or for the prevention of normal fatigue states.

Ritalin is contraindicated in patients with or without prior seizures, with or without EEG abnormalities, even in absence of seizures. Safe concomitant use of anticonvulsants and Ritalin has not been established. If seizures occur, Ritalin should be discontinued.

Use cautiously in patients with hypertension. Blood pressure should be monitored at appropriate intervals in all patients taking Ritalin, especially those with hypertension.

Drug Interactions

Ritalin may decrease the hypotensive effect of guanethidine. Use cautiously with pressor agents and MAO inhibitors. Ritalin may inhibit the metabolism of certain drugs, including antidepressants (phenothiazines, clomipramine, imipramine, propantheline), phenbutazone, and tricyclic antidepressants (imipramine, desipramine). Downward dosage adjustment of these drugs may be required when given concomitantly with Ritalin.

Use in Pregnancy
Adequate animal reproduction studies to establish safe use of Ritalin during pregnancy have not been conducted. Therefore, until more information is available, Ritalin should not be prescribed for women of childbearing age unless, in the opinion of the physician, the potential benefits outweigh the possible risks.

Drug Dependence
Ritalin should be given cautiously to emotionally unstable patients, such as those with a history of drug dependence or alcoholism, because such patients may increase doses and then become tolerant. Chronically abusive use can lead to marked tolerance and psychic dependence with varying degrees of abnormal behavior. Frank psychotic episodes can occur, especially with parenteral abuse. Careful supervision is required during drug withdrawal, since severe depression, as well as the effects of chronic overactivity can be unmasked. Long-term follow-up may be required because of the patient's basic personality disturbances.

PRECAUTIONS
Pulse, with an element of agitation, may react adversely to discontinuous therapy. If necessary, periodic CBC, differential, and platelet counts are advised during prolonged therapy.

ADVERSE REACTIONS

Nervousness and insomnia are the most common adverse reactions but are usually controlled by reducing dosage and omitting the drug at bedtime. Other common adverse reactions include hypertension (including skin rash, urticaria, fever, arthralgia, exfoliative dermatitis, erythema multiforme with histopathological findings of necrolytic vasculitis and thrombocytopenia), anorexia, nausea, dizziness, palpitation, tachycardia, hypertension, blood pressure and pulse changes, both up and down, tachycardia, epiphysis, cardiac arrhythmia, abdominal pain, weight loss during prolonged therapy. Toxic psychosis has been reported, although a causal relationship has not been established. The following have been reported in patients taking this drug: leukopenia and/or anemia; a few instances of scalp hair loss.

In children, loss of appetite, abdominal pain, weight loss during prolonged therapy, insomnia, and tachycardia may occur more frequently than in adults. Other adverse reactions listed above may also occur.

DOSE AND ADMINISTRATION

Adults

Administer orally in divided doses 2 or 3 times daily, preferably 30 to 45 minutes before meals. Dosage will depend upon indication and individual response.

Average dosage is 20 to 30 mg daily. Some patients may require 40 to 60 mg daily. In others, 10 to 15 mg daily will be adequate. The few patients who are unable to sleep if medication is taken late in the day should take the last dose before 6 p.m.

HOW SUPPLIED

Tablets, 20 mg (peach, scored); bottles of 100 and 1000.

Tablets, 10 mg (pale green, scored); bottles of 100, 500, 1000 and Accu-pak blister units of 100, 500, 1000.

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Wednesday, April 16, 1975

MEDICAL TRIBUNE

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Medical Tribune

and Medical News

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Genetic Engineering

THE INTERNATIONAL CONFERENCE ON Recombinant DNA Molecules, which met in late February in Asilomar, Calif., has drawn up a list of recommendations on precautions to be taken by investigators working in the field of genetic engineering (see page 5). Technical skills now available make it possible with the use of certain enzymes to cleave DNA at specific sites and join DNA from animal viruses with bacterial DNA or with viral DNA. The possibilities include illumination of the very basics of gene action.

But a year and a half ago, the potential hazards of "new kinds of hybrid plasmids or viruses, with biological activity of unpredictable nature" was raised at the 1973 Gordon Conference on Nucleic Acids. A Committee on Recombinant DNA Molecules, chaired by Professor Paul Berg of the biochemistry department at Stanford University, was formed in 1974 and in July called for a voluntary suspension of certain types

of genetic manipulation until a conference of workers in the field could be held to spell out precautions and tabus.

The precautions discussed at the conference include the high skills of the investigators themselves, the careful laboratory practices needed, and the use of biological barriers, such as organisms capable of survival only in the special environments of laboratories and not in natural environments.

Nobel Laureate Joshua Lederberg has expressed the fear that safeguards and precautions "that are entirely appropriate for certain risks might be prematurely rigidified into a set of bureaucratic regulations that might be very readily enforced beyond the domain of their reasonable application." That is a more than reasonable fear but, at this time, the precautions and the safeguards are in the hands of the investigators themselves. It is up to them to keep control in their own hands and out of the hands of bureaucrats.

Solving the Riddle of Diabetes Mellitus

IT IS NOW 54 years since Banting and Best demonstrated that an extract of the islet tissue of the pancreas can lower the blood sugar of the diabetic dog. Although the successful preparation of insulin extracts seemed at first to have solved the riddle of diabetes mellitus, this enthusiastic belief soon waned. Indeed, in the past quarter of a century, the puzzling questions about the etiology and pathogenesis of diabetes have multiplied rather than diminished as the techniques for investigating the disease have become more sophisticated and precise.

There are many reasons why the definition of diabetes mellitus as simply a disorder resulting from a relative or absolute deficiency of insulin secreted by the beta cells of the pancreas is unsatisfactory. For the past several years, Dr. Roger H. Unger of the Veterans Administration Hospital in Dallas, Texas, and the U. of Texas Southwest Medical School, has championed the notion that the disease is a bihormonal disease, "which holds that the major consequence of absolute or relative insulin lack is glucose underutilization and that absolute or relative glucagon excess is the principle factor in the overproduction of glucose in diabetes."

There is powerful evidence in support of this concept. The alpha cells of the pancreas secrete glucagon, which is known to be a hyperglycemic hormone. There has been ample demonstration since the late 1960's that every form of diabetic and non-diabetic hyperglycemia investigated "is accompanied by relative or absolute hyperglucagonemia."

Since the discovery of somatostatin, the hypothalamic growth hormone-releasing-inhibiting factor, it has been found to suppress both glucagon and insulin secretion. A series of brilliant investigations in Dr. Unger's laboratory and in a number of independent laboratories have demonstrated that hyperglycemia in dogs made insulin-deficient by alloxan or total pancreatectomy is abolished by somatostatin injection.

Dr. John E. Gerich and his colleagues at Dr. Peter Forsham's laboratory at the U. of California in San Francisco have recently reported that somatostatin injection in insulin-dependent diabetics reduced their plasma glucagon and hyperglycemia as well. As the investigators state: "The present findings have important therapeutic implications." What is needed is a preparation of somatostatin with a prolonged half-life. The exciting and intriguing possibility is that failure to prevent microangiopathy and atherosclerosis in diabetes by insulin therapy may be turned to success with the addition of somatostatin to the therapeutic regimen. Time will tell.

Hepatitis B Virus Carriers

Clinical Quote: "The significance of hepatitis B infection in early life lies...also in its importance in the genesis of prolonged carriage of hepatitis B virus. Zuckerman and Taylor (1969) described a well-documented healthy former blood donor carrying

hepatitis B antigen for at least 20 years. That a reservoir of chronic carriers may become established among children is, therefore, a cause for the utmost concern." (Dr. Arie Zuckerman, at a March of Dimes-National Foundation symposium on infections.



"I'll tell you something else I'm learning to live with!
Doctors who say, 'Learn to live with it!'"

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LETTERS TO TRIBUNE

Carotid Artery Palpation

I must take exception to one statement of Dr. Edwin Beven's (MT, Mar. 5).

Noninvasive or not—any palpation, compression, movement of adjacent structures, etc.—concerning a carotid artery with even minor stenosis cannot be considered a "No-Risk Method."

While the risk may be slight, the possibility of causing sudden, complete occlusion or cerebral embolization does exist and should be taken into consideration before even getting close to a patient's carotid artery. The presence of anomalous circulation, stenosis of other vessels, elevated lipoproteins, prior T.I.A.s and a variety of other factors will, of course, increase the risk.

DONALD M. POSNER, M.D.
Canaan, Vt.

New Laws Needed?

Dr. David Nathan is quoted (MT, Feb. 12) as follows "It never occurred to me that society would be worried that we will not maintain life." This must certainly strike a new low in what used to be called "life science" of medicine. Poor Dr. Nathan is so pre-occupied with what he sees on the other end of his telescope that he forgets that he is in the business of saving lives.

Irresponsible ivory tower pseudoscientists who have used unborn children as lab animals in vivisection-type experiments have created the need for new laws. They would like to use "hostility to abortion" as their whipping boy but the real culprit is their own ignorance of the Declaration of Helsinki.

THOMAS J. EGAN, M.D.
Chicago

Telling the Patient

Right on for Dr. Eli Friedman "Panelists Disagree on How Much To Tell Patient," (MT, Mar. 12)!

For the moment let us lay aside the complex and tricky question of whether or not to inform a patient if he or she is dying. Rather, let us consider the non-comatose patient of average intelligence. Even in the best run hospitals mistakes are made, orders scribbled illegibly on a patient's chart, residents and nurses carelessly or too hastily briefed on medications and/or general management of a case.

If the obstetrician has the right to destroy the live-born infant in an abortion procedure, would he not have the same right to extinguish the life of a newborn infant with a congenital defect whose mother may not want him?

The acceptance of this principle surely would, in fact, be providing a legal endorsement of euthanasia.

MATTHEW J. BULFIN, M.D.
President
Lauderdale-By-The-Sea, Fla.

Wednesday, April 16, 1975

Nitroglycerin Reported 'Consistently Beneficial' in Infarction

Continued from page 1

sign of hypotension and reflex tachycardia they have also administered the vasoconstrictor phenylephrine to mitigate these two side effects.

In general, Dr. Epstein noted, M.I. patients fall into two subgroups. One consists of those in heart failure, with elevated pressures and inadequate pumping action. "In this group, nitroglycerin appears to be very effective in reversing the manifestations of heart failure," Dr. Epstein said. "The high pressures that build up in the lungs decrease to normal very abruptly after nitroglycerin administration and the heart starts pumping more effectively. That's not new; these effects have been demonstrated by groups at Cedars of

Lebanon Hospital in Los Angeles, at Massachusetts General Hospital, and at Johns Hopkins. But what we have found in addition is that the size of the infarct, the amount of muscle damaged, is significantly reduced by treatment with nitroglycerin."

Non-Heart-Failure Group

The second subgroup of patients are those who have suffered a heart attack. Dr. Epstein continued, who have damaged muscle, but are not in heart failure. These patients are not usually treated, he said, "but nevertheless about 10 per cent of them die in hospital and another 10 per cent die within a year, so it is not a benign disease. In this subgroup of patients who have never been

treated before, we found exactly the same thing. We didn't get them out of failure, because they weren't in failure to begin with, but we found that the combination of nitroglycerin and phenylephrine reduced infarct size."

Dr. Epstein noted also that it is the second subgroup of patients that most often requires the phenylephrine to reverse the side effects of the nitroglycerin. And in the future, he said, he and his associates plan to give the nitroglycerin intravenously so it can be monitored more readily and more precisely.

On the basis of their experience with animals, Dr. Epstein said he thinks the nitroglycerin exerts its beneficial effects in two ways: by increasing the amount of blood delivered to the ischemic area

via the collateral system, and by reducing the size of the heart chamber, thus decreasing myocardial tension and oxygen requirements.

Dr. Epstein is working with Dr. Kenneth M. Kent, Dr. Robert E. Goldstein, and Dr. David R. Redwood, of the N.H.L.I. Cardiology Branch, and Drs. Barrie Levitt and Norman Cagin, of Flower and Fifth Avenue Hospitals, New York. Dr. Jeffrey S. Borer, who is in London on sabbatical leave from the N.H.L.I., is also participating in the trials.

Whether the treatment increases long-term survival is yet to be ascertained, Dr. Epstein said. But he thinks it has "enormous potential" and that long-term studies should be mounted. Dr. Epstein's animal studies are described in the January 2, 1975, *New England Journal of Medicine*, and preliminary clinical data appear in the April *Journal of Clinical Investigation*. Dr. Borer will present the full clinical report to the American Society of Clinical Investigation in May.

The epidemiological methods that eventually brought about the 10 per cent reduction in hospital onset infections at St. Luke's were scrutinized both during the formal study period and during a brief pre-computer programming study in 1969. "In the earlier study we wanted to validate the effectiveness of the nurse-epidemiologists since many physicians at the time doubted their ability to accurately collect data. In comparing three fellows in the infectious disease section with two nurse-epidemiologists over two week period we found that the latter were 94 per cent as effective as the former in collecting and classifying data on infections, which is not a statistically significant difference. We specifically restudied this question several times throughout the next four years and found that the nurses were consistently as accurate as the physicians trained in infectious diseases.

"In the earlier study," Dr. Edwards added, "we also wanted to find out how many nurses are needed per number of beds to do the job and how often they need to visit the wards. Basically we concluded that one nurse was required for 300 beds and that they needed to visit the wards twice a week.

After it was decided that we needed three nurses for our 840 beds, we hired an additional nurse."

Combined Approach Used

Once a full-blown infection control program was launched at Presbyterian-St. Luke's in 1969, a combined epidemiological and teaching approach was followed. "There are four different approaches that hospitals may take," commented Dr. Edwards. "First, many hospitals merely have a perfunctory infection control committee that meets in order to fulfill accreditation requirements but doesn't really do anything about the endemic level of hospital infections and only becomes active if there is an outbreak. Unfortunately I suspect that this is the most common approach. Second, there is the commando approach, in favor of which physicians will argue that we already know what most of the problems are so let's go out and work on those and also be ready to investigate any epidemics that may come up. Unquestionably that approach will lower the infection rate at some sites at some hospitals, depending on the interests of the people who are commanding the commandos, as it were. But it doesn't tell much about whether one is getting a total impact and a uniformly educated hospital staff to reduce the overall problem over the long haul.

"The third approach is what one might call the surveillance approach that the underlying disease is determining in most cases, but at the same we concluded that if one can prevent some of the infections in the 12.9 per cent category, then one can reduce mortality as well as morbidity."

"The fourth approach is the epidemiological one in which you do essentially all of the things that the other approaches do plus actively inform and instruct."

"Something I've always felt strongly about with respect to hospital infections in the context of total hospital mortality," Dr. Edwards indicated that about a fourth of patients who died at Presbyterian-St. Luke's between 1969 and 1973 had an infection of hospital origin at the time of death.

Wednesday, April 16, 1975

Control Program Credited With 10% Decrease in Hospital Infections

Role of Community Onset Infections and Hospital Onset Infections in Deaths by Service From 1969 Through 1972

Role of Infection in Death

Service	Infection Primary Cause		Infection Associated		Underlying Disease Primary Cause	Underlying Disease Associated
	COI	HOI	COI	HOI		
Medicine	14.3	9.6	25.2	28.9	7.7	7.7
Surgery	14.3	18.7	18.7	22.0	10.4	10.4
Pediatrics	14.3	24.5	30.8	16.9	14.7	16.8
Newborns	0.0	18.7	33.5	20.7	1.1	1.1
Total Hospital	14.3	12.9	24.8	20.7	14.0	14.0

14.3 Presbyter-St. Luke's Hospital

Excludes as of 1970, 1971, 1972, 1973, 1974

COI = Community Onset Infection; HOI = Hospital Onset Infection

Mortality Associated With Community Onset Infections and Hospital Onset Infections By Services From 1969 Through 1972

Mortality Rates Associated With Community Onset & Hospital Onset Infection

Service	Per Cent of Admissions		Per Cent of Deaths		Number of Infections Per Death
	COI	HOI	COI	HOI	
Medicine	1.7	1.7	22.3	22.8	1.4
Surgery	0.9	1.1	15.1	12.0	1.2
Pediatrics	0.4	0.4	22.1	25.0	1.5
Newborns	0.0	1.3	11.3	6.3	1.8
Total Hospital	0.8	0.8	18.4	20.2	1.4

14.3 Community Onset Infection HOI = Hospital Onset Infection

Excludes as of 1970, 1971, 1972, 1973, 1974

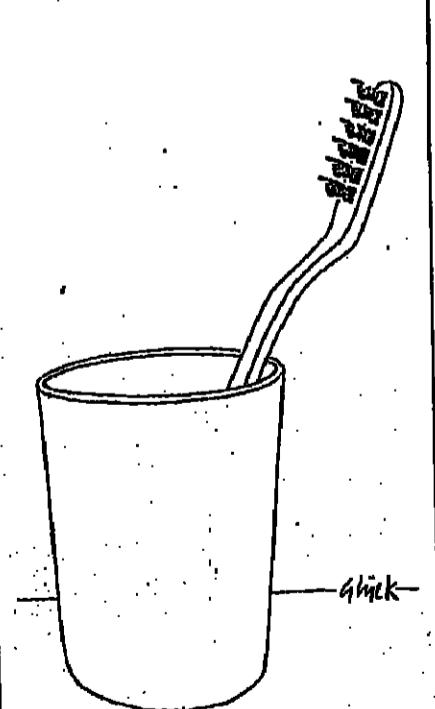
COI = Community Onset Infection; HOI = Hospital Onset Infection

rate of hospital employees today, the key to control isn't so much new knowledge as it is having some ongoing way of continually bringing the problem to people's attention, both in terms of education about how to perform certain procedures and in terms of epidemiological data so one can know whether one is making an impact. If we're not, then push harder in the particular area where we're not making an impact. I don't think one can make reasonable applications unless one knows what is going on in one's own hospital."

80% of Infections at 4 Sites

In the Presbyterian-St. Luke's study it was determined that about 80 per cent of the infections were occurring at four major sites—the urinary tract, lower respiratory tract, surgical wounds and bloodstream. "All of the sites had pretty much the same decrease in infections except for the bacteremias, which actually went up. In 1969 there were 969 urinary tract occurrences compared to 741 in 1972, 665 lower respiratory tract occurrences compared to 651, 520 surgical wound infections compared to 402, and 173 bacteremias compared to 233. The rise in bacteremias, I think, may be due to the fact that the hospital started doing more bowel cancer surgery."

An unusual aspect of the study, and one which requires further investigation, is that it was the first long-term study to look at the interchange between community onset and hospital onset infections. "We defined a community onset infection as one present on admission or coming up in the first 72 hours and not related to a hospital procedure. I don't think we have any hard and fast data on this interchange, but we got some inkling into where we need to look



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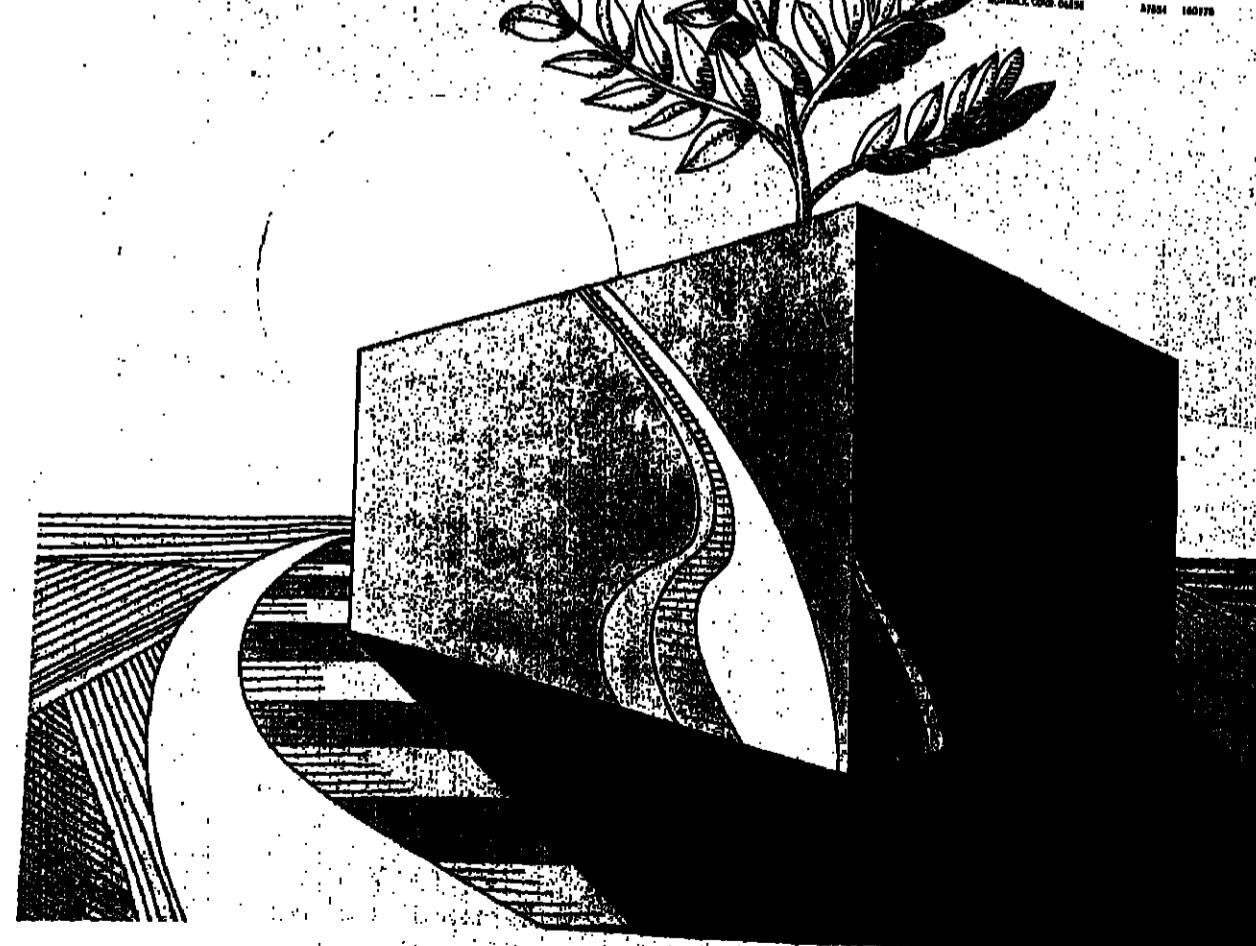
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Artist's conception of *Cassia acutifolia* plant.

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Interdisciplinary PG Training Program Set

By MICHAEL HERRING
Medical Tribune Staff

ROCHESTER, N.Y.—An interdisciplinary postgraduate training program at Strong Memorial Hospital utilizing internists, pediatricians, and specialists in the same physical setting—and in some cases operating as a fee-for-service private group practice—will go into full effect as soon as all services are moved into the new ambulatory care wing here, Dr. Warren Glaser, program coordinator, told MEDICAL TRIBUNE.

The program will provide for training at all levels, he said, and make physician services more readily available to all patients in the community, regardless of their ability to pay.

Effective Coordination Sought

"We can't sacrifice the expertise we've gained from so much specialization, but at the same time, there has to be a way to coordinate individual efforts more effectively," he explained. "The beauty of the arrangement at Rochester is that you have both the generalist and the specialists working compatibly and in close proximity."

Dr. Glaser, who is Professor of Medicine and coordinator of ambulatory care, Department of Medicine at the University of Rochester School of Medicine and Dentistry, said that the decision to form the hospital team of group-practice internists and pediatricians, with the backup of subspecialists in each major area, was based on the recognition that "the hospital stands at the center of the ambulatory health care system."

"Ideally," he said, "each person in the community should have access to a personal physician who renders comprehensive care with continuity and who can delegate that care when necessary to the appropriate specialist."

Primary care, he continued, should be medical attention that is "available and accessible" to the patient when he or she needs it. "Primary care should not refer only to the initial visit to a doctor during office hours, but includes empathy, continuity, and treatment that is appropriate to the patient's changing needs," he said.

Integrationist for Subspecialties

"At the same time, it should function to take the load off the emergency-room physician. Finally, the primary care physician is the integrationist for all medical subspecialties that the patient may require."

Dr. Glaser emphasized that the primary care physician at Strong Memorial will function increasingly as a member of a team—"not just with other doctors, but with nurses, social workers, and other medical and paramedical personnel."

"We think that the group practice of general internists and general pediatricians has more appeal," he commented, "because it is a higher level of care, and permits more appropriate referrals within the system."

Dr. Glaser briefly described the new arrangement at Strong Memorial as follows:

"In medicine, we have two or three interns, two assistant residents, and

two associate residents teamed with an attending physician and a licensed practical nurse. The whole team cares for a panel of patients."

In addition, he explained, the interdisciplinary group, together with the house staff, care for the medical clinic and combined clinic patients from the previous arrangement.

"These patients are now considered as one group of hospital patients, and are seen on a private-practice basis. Once a patient is entered into the system, the fees for hospital services and the fee-for-service practice are the same. Patients, no matter how they pay, can be transferred from one group to another. Obviously, we can't know all the patients, but we can provide care, based on the fact that this is a recog-

nized individual who has a problem. With all the groups working closely together, we have records and previous visits on which to base a judgment."

The continuity clinic is the pediatric counterpart to the house staff group, he added, but with a somewhat different organization. While the latter has interns, assistant residents, and associate residents working together, the pediatric group is a horizontal arrangement, with all interns, all first-year residents, and all second-year residents working together, Dr. Glaser said.

He also pointed out that "residents here are actually participating in the practice, and medical students are able to view their work first-hand and form their own judgment. Naturally, we want it to be good so that the most valuable physicians of the future are attracted to this kind of patient care."

ER Resident on Call

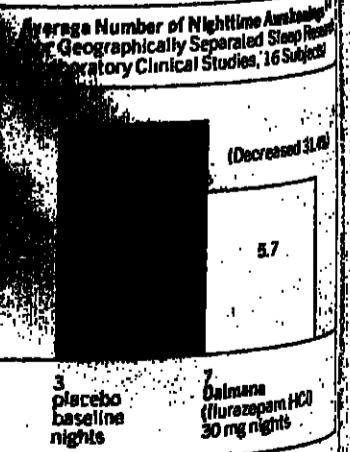
"Rather, the resident in the emergency room acts as the on-call physician in a manner similar to those in the internal medicine group covering for one another. Obviously, we can't know all the patients, but we can provide care, based on the fact that this is a recog-



Would sleep with fewer nighttime awakenings benefit your patients with insomnia?

Highly predictable results for your patients with trouble staying asleep...

...can be obtained with Dalmane (flurazepam HCl). As shown below, Dalmane significantly reduces nighttime awakenings.



Before prescribing Dalmane (flurazepam HCl), please consult complete product information, a summary of which follows:

Indications: Effective in all types of insomnia characterized by difficulty in falling asleep, frequent nocturnal awakenings and/or early morning awakenings; in patients with recurring insomnia or poor sleeping habits; and in patients with insomnia associated with acute or chronic medical situations requiring restful sleep. Since insomnia is often transient and intermittent, prolonged administration is generally not necessary or recommended.

Contraindications: Known hypersensitivity to benzodiazepine HCl.

specifically indicated for insomnia

Objectively proved in the sleep research laboratory:

- sleep with fewer nighttime awakenings
- sleep within 17 minutes, on average
- sleep for 7 to 8 hours, on average, with a single h.s. dose.



ROCHE LABORATORIES
Division of Hoffmann-La Roche Inc.
Nutley, New Jersey 07110

One Man... and Medicine

ARTHUR M. SACKLER, M.D.
International Publisher, Medical Tribune



Now, A Word From the Opposition

MEDICAL TRIBUNE supports the free exchange of differing views. The following letters are some of the responses to Dr. Sackler's column on the Edelin case, "Doctor, Are You Innocent?" (MT, Mar. 12).—Ed.

Your newspaper's coverage of the Edelin conviction is worthy of the 1984 Black is White Literary Award. The "straight" news story by a Special Cor-

respondent sets the tone in the headline—Shock and Dismay—with the predictable bias in the body of the story. Flanking this, we find a "Special Trib-

une Report" by the same author and your sterling piece, "Doctor—Are You Innocent?"

You and your newspaper seem somehow to have missed a basic point. A jury of his peers found Dr. Edelin guilty of manslaughter. He did not kill a fetus—he killed a living human being.

Please remove my name at once from your mailing list.

WILLIAM DANIEL DAVIES, M.D.
Evanston, Ill.

more interesting and deserving to sustain the name of good medicine which is being evaded daily by the very act about which he brags. Let us have no more of this, please. Thank you.

Incidentally, the editorial by Arthur M. Sackler, M.D., was about as enlightening as an overflowing commode.

GERARD A. DEL GRIPPO, M.D.
Lock Haven, Pa.

The vile and vicious anti-Catholic tone of your editorial leads me to make this protest of your appeal to the worst instincts of the society. The kind of abortion performed by Dr. Edelin is disapproved by all segments of the society, all religions, and even a majority of atheists (see Blake, J., *Science*, April 1972).

The tortured non-scuities of your argumentation lead me to believe that you were blinded by bigotry in departing from your usual well-reasoned rationale. You find it incomprehensible that a man could be found guilty of manslaughter in "standing by and denying a fetus oxygen and thereby causing its death." Willfully to deny a person oxygen which might have prolonged its life has always been a crime. This is, after all, what the Boston strangler did. Dr. Edelin's true "peers" are said to be his fellow abortionists. Why not have the Godfather judged by his fellow Mafioso?

The jury in Boston (whose religion is unknown and irrelevant except to neo-Nazis) have called to issue that notion that every termination of life done under the rubric of "medical procedure" is not to be tolerated by decent Americans.

EUGENE F. DIAMOND, M.D.
Chicago

Regarding Dr. Sackler's editorial on the Edelin case, I am surprised at such verbal frothing-at-the-mouth. Dr. Sackler has always seemed like such a calm, cool, deliberate thinker. It's so unlike him. Does he really mean to compare the culpability of food manufacturers in producing coronary disease (a rather far-fetched and tenuous theory at best) with the deliberate actions and inactions of Dr. Edelin? Dr. Edelin, in essence, delivered a premature baby by C-section, and then *deliberately neglected* it to death, by his own admission.

As Dr. Sackler suggests, Dr. Edelin's conviction will probably be overturned—because of technical flaws in his trial—but not because his actions, *per se*, were so noble. He may or may not be guilty of manslaughter, but on the other hand, it ill-behooves so many physicians to make a hero of him, or to publicly applaud his second-trimester "abortion" activities as a prototype of conduct which all physicians should emulate.

Such an attitude is unlikely to rebound to our credit in the future.

Out of embarrassment for Dr. Sackler, I will merely pass over his not-so-subtle appeal to religious bigotry, without further elaboration.

As for emotionalism, it surely looks like the shoe is on the other foot this time.

JAMES H. FORD, M.D.
Lynwood, Calif.

We know Librium works. (chlordiazepoxide HCl)

We're still learning more about how and why.

Value of continuing animal research

Clinical knowledge of Librium is extensive, yet its mode of action remains under continuing study. Data from animal experiments have been presented here for their intrinsic interest and because such findings often provide direction to new research, both experimental and clinical. *However, conclusions from such studies may not always be extrapolated to humans.*

Is the limbic system the "Librium (chlordiazepoxide HCl) system"?

A great deal of experimentation on various animal species suggests that the limbic system is the principal site of action of Librium. Thus, in freely moving cats with electrodes implanted in the brain, Librium 5 mg/kg i.p. slowed electrical activity in the hippocampus, amygdala and septal areas but not in the neocortex which was significantly affected only at higher doses.^{1,2} Current investigations on monkeys,^{3,4} however, indicate that other subcortical structures may be implicated in the effect of Librium.

Other investigators, through electrophysiologic studies⁵ in intact, conscious cats and monkeys, have demonstrated that chlordiazepoxide activates structures involved in the rewarding system—the preoptic area, lateral hypothalamus, septal region and hippocampal formation. At the same time, it appears to *inhibit* structures implicated in aversive behavior—the thalamic nuclei of the diencephalon and the midbrain reticular formation (MRF).

References:

1. Schalek W, Kuehn A, Jew N: *Ann NY Acad Sci* 90:303-312, Jan 1962.
2. Sternbach LH, Randall LO, Gustafson SR: 1,4-Benzodiazepines (Chlordiazepoxide and Related Compounds), chap. 5, in *Psychopharmacological Agents*, edited by Gordon M. New York, Academic Press, vol. 1, pp. 173-178.
3. Delgado JMR, Brucetta II, Snyder DR: *Psychoactive Drugs and Radio-Controlled Behavior*. Film presented at the 124th annual meeting of the American Psychiatric Association, Washington DC, May 3-6, 1971.
4. Delgado JMR: *Antigressive effects of chlordiazepoxide*, in *The Benzodiazepines*, edited by Gurattini S, Mussini E, Randall LO. New York, Raven Press, 1973, pp. 419-432.
5. Guererro-Figueroa R, et al: *Electrophysiological analysis of the action of four benzodiazepine derivatives on the nervous system*, *Ibid.*, pp. 489-511.



Before prescribing, please consult complete product information, a summary of which follows:

Indications: Relief of anxiety and tension occurring alone or accompanying various disease states.

Contraindications: Patients with known hypersensitivity to the drug.

Warnings: Caution patients about possible combined effects with alcohol and other CNS depressants. As with all CNS-acting drugs, caution patients against hazardous occupations requiring complete mental alertness (e.g., operating machinery, driving). Though physical and psychological dependence have rarely been reported on recommended doses, use caution in administering to addiction-prone individuals or those who might increase dosage with withdrawal symptoms (including convulsions),

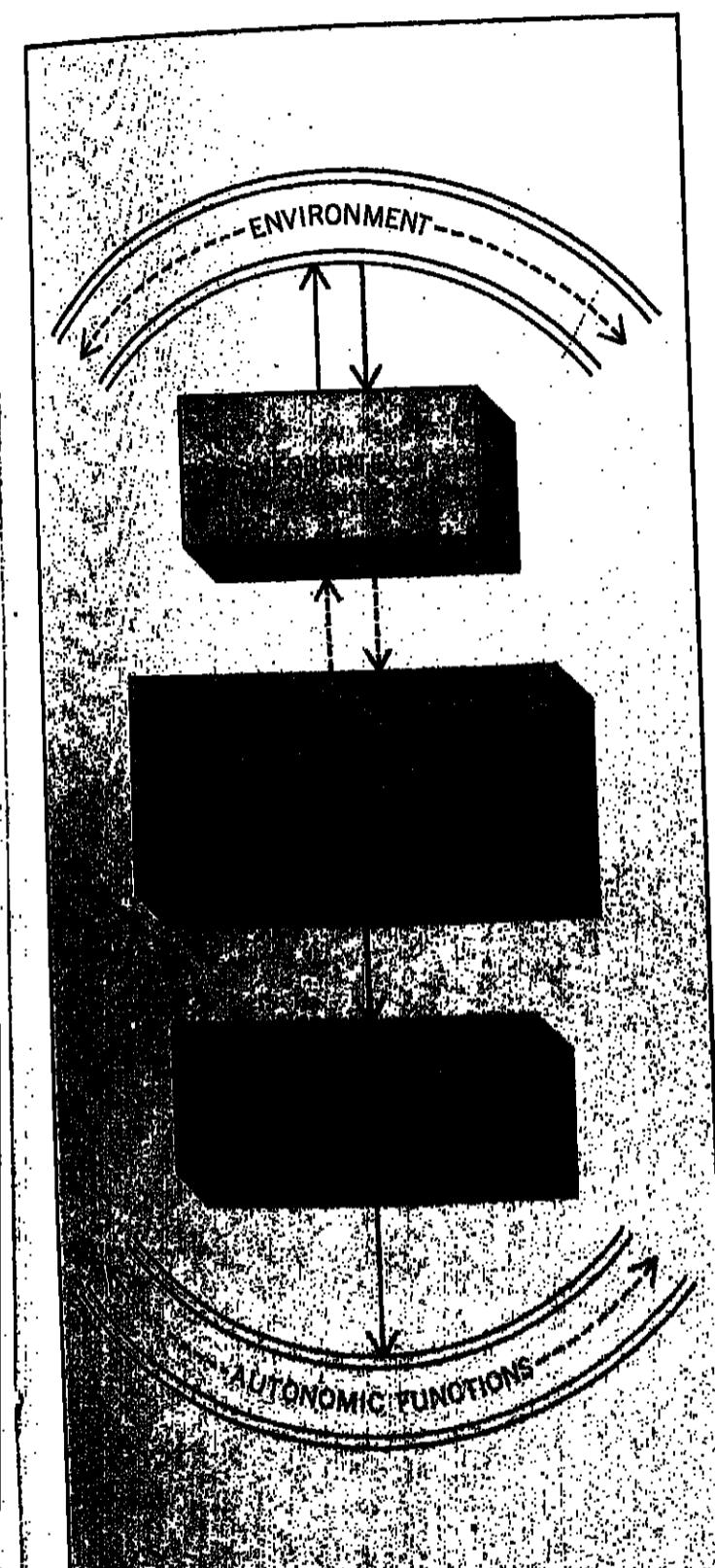
following discontinuation of the drug and similar to those seen with barbiturates, have been reported. Use of any drug in pregnancy, lactation, or in women of childbearing age requires that its potential benefits be weighed against its possible hazards. **Precautions:** In the elderly and debilitated, and in children over six, limit to smallest effective dosage (initially 10 mg or less per day) to preclude ataxia or oversedation, increasing gradually as needed and tolerated. Not recommended in children under six. Though generally not recommended, if combination therapy with other psychotropics seems indicated, carefully consider individual pharmacologic effects, particularly in use of potentiating drugs such as MAO inhibitors and phenothiazines. Observe usual precautions in presence of impaired renal or hepatic function. Parti-

cular reactions (e.g., excitement, stimulation and acute rage) have been reported. In psychiatric patients and hyperactive aggressive children. Employ usual precautions in treatment of anxiety states with evidence of impending depression; suicidal tendencies may be present and protective measures necessary. Variable effects on blood coagulation have been reported very rarely in patients receiving the drug and

oral anticoagulants; causal relationship has not been established clinically. **Adverse Reactions:** Drowsiness, ataxia and confusion may occur, especially in the elderly and debilitated. These are reversible in most instances by proper dosage adjustment, but are also occasionally observed, at the lower dosage ranges. In a few instances syncope has been reported. Also encountered are isolated instances of skin eruptions, edema, minor menstrual irregularities, nausea and constipation, extrapyramidal symptoms, increased and decreased libido—all infrequent and generally controlled with dosage reduction; changes in EEG patterns (low-voltage fast activity) may appear during and after treatment; blood dyscrasias (including agranulocytosis), jaundice and hepatic dysfunction have been reported occasionally, making

periodic blood counts and liver function tests advisable during protracted therapy. Supplied: Librium® Capsules containing 5 mg, 10 mg or 25 mg chlordiazepoxide HCl. Libritabs® Tablets containing 5 mg, 10 mg or 25 mg chlordiazepoxide.

ROCHE Roche Laboratories Division of Hoffman-La Roche Inc., Nutley, New Jersey 07110



Schema demonstrating hypothetical pathways of emotional activity and its related expression in laboratory animals.

Clinical significance of excessive anxiety

Anxiety, when inappropriate and immoderate, may not only have adverse psychologic effects but may also cause various somatic disturbances. Reduction of excessive anxiety thus contributes to relief of anxiety-linked emotional and physical disorders.

Antianxiety action of Librium (chlordiazepoxide HCl)

The dependable action of Librium has been demonstrated in the relief of excessive anxiety and tension occurring alone or in association with functional and organic disorders—usually without adversely affecting performance. Librium is often used concomitantly, when anxiety is a contributing or complicating factor, with certain specific medications of other classes of drugs, e.g., cardiac glycosides, diuretics and antihypertensives.

Adjunctive use of Librium is recommended when counseling, reassurance or other nonpharmacologic measures alone are not considered sufficiently effective. When anxiety has been reduced to manageable levels, therapy with Librium should be discontinued.

Librium®
(chlordiazepoxide HCl)
5 mg, 10 mg, 25 mg capsules



We're still learning more about it
to make it more useful to you.

wine talk

By JOHN CHAMBERS
Author and Consultant to
Morrell & Company,
New York Wine Merchants

Aging Wine

DR. ARTHUR BIEGANOWSKI of New York is one of the most ardent wine enthusiasts of my acquaintance. Indeed, at his home it would be almost an insult to ask for Scotch. He has a genius for coming up with surprises, and his latest was a master stroke. Somehow he had managed to find a bottle of ruby port that had lain in a cellar over 30 years. To taste the delicacy and beauty of this comparatively inexpensive, generally available wine, given 30 years' aging, was a potent reminder of what age can do for a wine with the capacity to respond to it.

Some wines do not need aging and are best drunk very young. These are light wines—rosés and whites for the most part, and a few of the lightest reds like Beaujolais, Bardolino, or inexpensive Chianti. Only the better white Burgundies and Graves, the Pinot Chardonnays of California, Barsacs and Sauternes, the white Rhônes, and the spilates, austuses, and up of Germany need more than a year or two in the bottle, and of these, only the white Rhônes, Barsacs, Sauternes, and sweater German wines can be kept with impunity beyond seven years.

With red wines the problem of aging becomes more complicated. Here it is not only a question of a particular wine, but also the character of a vintage. For example, most of the 1967 red Bordeaux are ready for present drinking, whereas the bigger 1966's are a year or two away. The best rule of thumb is that red Bordeaux from the Médoc require seven years, from St. Emilion and Pomerol six years, and from elsewhere in Bordeaux four years. If the vintage is listed as a "long-lived" one, add a year or two.

Burgundy Needs Less Time

Red Burgundy is ready sooner. Wines from the Côte de Nuits require six years in a big vintage, whereas most Côte de Beaunes are ready in four years. Only the biggest Beaujolais will improve beyond three years. In the Rhône valley the biggest wines require seven years of bottle age in most vintages, but Côtes du Rhône (one of the better buys on the market) need only two to three years. The same holds true of the Loire reds and of the so-called country reds from elsewhere in France.

In Italy, Spain, and Portugal, price is a fair guide to aging requirements. The more expensive wines need six to seven years in the bottle, while two to three years is sufficient for the less expensive. The other red wines of Europe can generally be drunk when marketed.

Most reds from North and South America can also be drunk when purchased, the major exceptions being the better California Cabernet Sauvignons, Petite Sirahs, and Zinfandels, all of which benefit from additional bottle age.

Next Month: Research and Viniculture

Strike Pact Terms May Have Wide Impact

Continued from page 1

hospital, consisting of an equal number of members from staff and administration, and charged with formulating "appropriate work schedules" and hearing grievances. Salaries, which now range from \$13,500 for an intern to \$19,200 for a 6th year resident (PGY 7) will rise 8 per cent, with an across-the-board cost of living sum of \$250 added.

Broad Impact Foreseen

Dr. Robert G. Harmon, president of the Physicians National Housestaff Association, which supported the strike, told MEDICAL TRIBUNE that he thought the point would not be lost on "exploitative" hospital administrators and senior staff everywhere.

"It's a major victory, and it's going to give momentum to National Labor Relations Board negotiations for reasonable hours and working conditions in many hospitals—for example, Los Angeles County Hospital and the District of Columbia Children's Hospital," Dr. Harmon said. He noted that Dr. Malcolm C. Todd, president of the A.M.A., had given his blessing to the strike, a move that surprised some and could not help enhancing the possibility of similar changes, if not strikes, elsewhere.

Dr. Todd's statement said in part that "in important respects, this is a strike for better patient care . . . When a physician has to work 50 hours straight or 100 hours in a week, it is not only tough on him or her, it is also a threat to the quality of care the patient is receiving."

Hospitals Reject Implications

A spokesman for the A.M.A. told MEDICAL TRIBUNE that although the Association expected criticism from its membership concerning the Todd statement, little had yet been received. However, officials of the struck hospitals in New York vigorously rejected the implications of the statement, saying that the League of Voluntary Hospitals included some of the finest medical facilities in the world and would never do anything that threatens patient care.

Jess Solivan, president of the League, backed Dr. Pomrinse. Regardless of scheduling, he said, "It's expected that when a doctor reaches the point where he's not able to produce or avail himself of the learning process, he'll say, 'Hey, give me some relief!'"

This just isn't so, contended Dr. Mark Fleischer, a medical intern on the picket line at Brookdale Hospital Medical Center in Brooklyn. "What

Continued on page 19.



In the first doctors' strike recorded in the U.S., picket lines surrounded some of the most prestigious hospitals in the country, including Mount Sinai, above.

are you going to do at 3:00 A.M.? Call your buddy, who's in the same condition you are and say, 'Hey, give me some relief!'"

An attending physician at one of the struck hospitals confirmed Dr. Fleischer's statements. This physician, who wished to remain anonymous, recalled that when he took his internship at Montefiore Hospital and Medical Center in the Bronx, which was also affected by the strike, some few interns did call for help from their chiefs of service.

Retaliation Recalled

"In most cases they got it," he related. "But they always paid for it later. They were branded as weak sisters who couldn't take the strain of being a doctor, and in some cases I know of, they weren't asked back to take their residencies at Montefiore the following year."

And Dr. Don Rubin, a medical intern at Mount Sinai, pointed out that a house officer on a 36- to 48-hour tour

Continued on page 19.

Wednesday, April 16, 1975

Continued from page 18
of duty may actually get less sleep than Dr. Pomrinse did on his 60-hour shifts. "Medicine has become much more complex in recent years," said Dr. Rubin, who took his turn on the picket line at his institution. "There's much more that we can do for patients."

"For instance, when a patient went into cardiac arrest in Dr. Pomrinse's time, the intern signed the death certificate and went back to bed. Today, he's going to be working with the cardiac emergency team for at least two hours, saving the patient's life."

"And it's the same with peritoneal dialysis, which they didn't have until the early 1960s. If a patient needs dialysis today, he doesn't die. But I'm sitting up all night with him."

Out-of-Title Work Cited

Dr. Rubin tied the demand for shorter hours to the out-of-title work issue. "A lot of what I do, especially at night, isn't doctor work. Watching that dialysis patient should be done by a nurse, with me on call. And I spend a lot of time wheeling patients around in the hospital or delivering bloods to the lab."

Not all the house officers at League hospitals went out on strike. At Brookdale, for instance, many of the senior medical residents stayed on, while most of their junior colleagues walked the picket line.

"Some of us were angry about that," Dr. Fleischer said. "But in a way, it made things easier on me to know there were doctors in there taking care of the patients."

Most of the striking house officers felt as Dr. Fleischer did, and at many of the struck institutions the house officers made arrangements with the hospital to provide emergency patient care.

"This doesn't mean we didn't support the aims of the strike," said one pediatric resident there. "A lot of us did. We just didn't feel that a strike was the right way to do it."

The decision to walk out was a major one for the C.I.R.'s strike committee. "It was forced on us by the



League of Voluntary Hospitals officials announcing strike settlement. Clockwise from lower left, William A. Ahelow, executive director, Jess Solivan, president, Norman Metzger of Mount Sinai Hospital, and Alan Abramson of Montefiore.

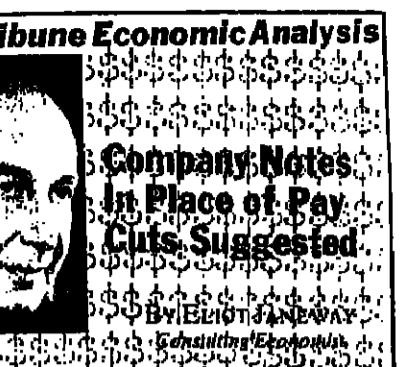
League," charged Dr. Richard A. Knutson, president of the C.I.R. "Our contract ended September 30. We negotiated with the League until December, and we were before a federal board of inquiry, set up by the National Labor Relations Board, through January."

Only Permissible Job Action
"We were willing to accept the federal factfinder's recommendations, which included a recommendation that duty hours and out-of-title work be negotiated further. But the League wouldn't negotiate."

Dr. Knutson also contended that a strike is the only form of job action the C.I.R. is permitted to take under the National Labor Relations Act, which was extended to voluntary hospitals last year. Other measures—work slowdowns and refusal to perform paper-work for third-party reimbursement—were labelled unfair tactics by the federal legislation.



C.I.R. Photos
Left, a surprised Dr. Anthony Bottone, C.I.R. delegate, holds aloft news of A.M.A. support. Above left, delegates found negotiating almost as tiring as duty schedules they sought to change. Above right, Dr. Diane Chen-Cohen, Long Island Jewish-Hillside Medical Center delegate, checks in while colleague catnaps.



Tribune Economic Analysis
Company Notes
In Place of Pay Cuts, Suggested
By Edward Knutson
Editorial Page Editor

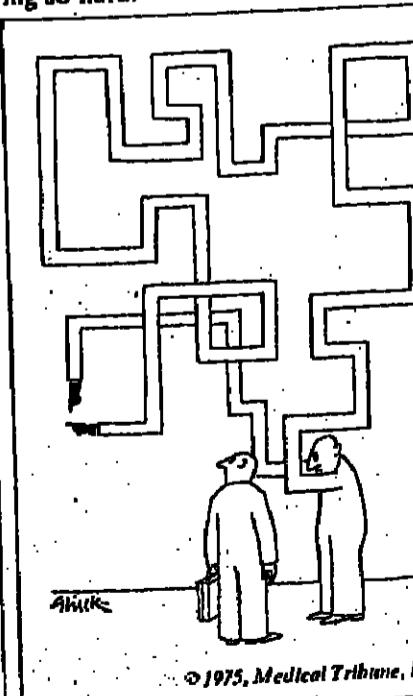
The very magnitude of today's debt burden offers a handle for avoiding a repeat performance of the 1930s depression that is clearly threatening. Over-indebtedness is the specific abuse responsible for hyper-inflation. Booms invite an overload of debt, which accentuates busts.

The sound way to undo today's damage, and to avoid still more, is to lighten the debt load by trading on the troublesome fact that people on payrolls are struggling with every bit as cruel a debt overload as outlays to meet payrolls. The banks are at least as anxious over the consequences of their over-lending as their debtors are over the consequences of their over-borrowing.

A 3-Way Compromise

The wobbling companies, their anxious banks, and the petrified people on their payrolls would be ahead if they worked a three-way compromise. Assume that the management in trouble could show both the banks on its back and the people on its payroll how much difference a reasonable cut would make. And that management demonstrated its good faith by practicing austerity on expense accounts and taking an appropriate cut itself. All three partners in the debt squeeze would be ahead if management "borrowed" the pay cut from labor instead of just taking it.

Issuing company notes to everyone on the payroll in order to cover the cut agreed upon would kill three birds with one stone. Management would cut costs. People now worrying that each paycheck might be the last would get a new asset with a fighting chance to keep the money coming. The banks would wind up with a better-fixed business borrower, plus a whole new group of family circle customers for the consumer installment loans they are pushing so hard.



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Delegates of Committee of Interns and Residents take a straw vote on contract offer by the League of Voluntary Hospitals during negotiations.

C.I.R. Photo

"Let me tell you about the medicine I'm going to prescribe."

TALKING OVER VALIUM®(diazepam) THERAPY WITH YOUR ANXIOUS PATIENT



And it's also good for him to realize that he will be taking Valium only as long as he needs it.

Your expressed confidence in the medication prescribed, and the positive atmosphere in which therapy is given and accepted, work to the patient's advantage.

A patient often benefits by a greater understanding of his treatment program. You may find it helpful to make your patient aware that the purpose of therapy with Valium is to help reduce discomforting and disabling symptoms of excessive psychic tension and anxiety. It is beneficial for him to understand that much of his tension and anxiety can be relieved by your reassurance and counseling, and that these measures can do more than anything else to help him cope with his basic problems. The patient is reassured in knowing he can expect his medication to help him avoid feeling overwhelmed by his symptoms.

Selection of a dosage regimen is an important consideration when Valium (diazepam) is prescribed, and dosage should be individualized to achieve maximum beneficial effect. If the patient understands clearly when and how much to take, and if he knows why it's to his benefit to follow the regimen closely, the chances are better that he will take the medication precisely as directed. That should help avoid missed doses and discourage taking too much or too little medication—all of which can have an undesirable effect on the management of the patient's condition.

*"It's important that you
follow my directions
closely."*

*"I'll see you again the week
after next and we'll see
how you're making out."*

Your patient is often likely to feel reassured when you talk about seeing him again to check his progress. A planned visit evidences your continued interest and affords the patient an opportunity to report improvement he has made and to relate whatever continuing or additional difficulties he may be experiencing. It's also a chance for him to describe his response to therapy with Valium.

During follow-up visits, as your patient talks about his medication and about its effects on his symptoms, he will provide the kind of information that will be of great help in evaluating total therapy, adjusting the dosage of Valium, or discontinuing the medication entirely if that seems indicated.

Valium®(diazepam)
2-mg, 5-mg, 10-mg scored tablets
for individualized treatment of psychic tension



Please see the following page for a summary of product information.



Valium® (diazepam)

2-mg, 5-mg, 10-mg scored tablets

Prompt, effective action. Valium (diazepam) works rapidly to relieve pronounced psychic tension in patients overreacting to stress and in psychoneurotic patients.

Before prescribing, please consult complete product information, a summary of which follows:

Indications: Tension and anxiety states; somatic complaints which are concomitants of emotional factors; psychoneurotic states manifested by tension, anxiety, apprehension, fatigue, depressive symptoms or agitation; symptomatic relief of acute agitation, tremor, delirium tremens and hallucinosis due to acute alcohol withdrawal; adjunctively in skeletal muscle spasm due to reflex spasm to local pathology; spasticity caused by upper motor neuron disorders; athetosis; stiff-man syndrome; convulsive disorders (not for sole therapy).

Contraindicated: Known hypersensitivity to the drug. Children under 6 months of age. Acute narrow angle glaucoma; may be used in patients with open angle glaucoma who are receiving appropriate therapy.

Warnings: Not of value in psychotic patients. Caution against hazardous occupations requiring complete mental alertness. When used adjunctively in convulsive disorders, possibility of increase in frequency and/or severity of grand mal seizures may require increased dosage of standard anticonvulsant medication; abrupt withdrawal may be associated with temporary increase in frequency and/or severity of seizures. Advise against simultaneous ingestion of alcohol and other CNS depressants. Withdrawal symptoms (similar to those with barbiturates and alcohol) have occurred following abrupt discontinuance (convulsions, tremor, abdominal and muscle cramps, vomiting and sweating). Keep addiction-prone individuals under careful surveillance because of their predisposition to habituation and dependence. In pregnancy, lactation or women of childbearing age, weigh potential benefit against possible hazard.

Precautions: If combined with other psychotropics or anticonvulsants, consider carefully pharmacology of agents employed; drugs such as phenothiazines, narcotics, barbiturates, MAO inhibitors and other anti-

Wide margin of safety. Valium is generally well tolerated and in usual dosages rarely produces significant adverse reactions. (See prescribing information below.)

Dosage flexibility. Scored Valium 2-, 5-, and 10-mg tablets give you dosage flexibility no tranquilizer capsule can match.

Depressants may potentiate its action. Usual precautions indicated in patients severely depressed, or with latent depression, or with suicidal tendencies. Observe usual precautions in impaired renal or hepatic function. Limit dosage to smallest effective amount in elderly and debilitated to preclude ataxia or oversedation.

Side Effects: Drowsiness, confusion, diplopia, hypotension, changes in libido, nausea, fatigue, depression, dysarthria, jaundice, skin rash, ataxia, constipation, headache, incontinence, changes in salivation, slurred speech, tremor, vertigo, urinary retention, blurred vision. Paradoxical reactions such as acute hyporexcited states, anxiety, hallucinations, increased muscle spasticity, insomnia, rage, sleep disturbances, stimulation have been reported; should these occur, discontinue drug. Isolated reports of neutropenia, jaundice; periodic blood counts and liver function tests advisable during long-term therapy.

Dosage: Individualize for maximum beneficial effect. **Adults:** Tension, anxiety and psychoneurotic states, 2 to 10 mg b.i.d. to q.i.d.; alcoholism, 10 mg t.i.d. or q.i.d. in first 24 hours, then 5 mg t.i.d. or q.i.d. as needed; adjunctively in skeletal muscle spasm, 2 to 10 mg t.i.d. or q.i.d.; adjunctively in convulsive disorders, 2 to 10 mg b.i.d. to q.i.d. **Geriatric or debilitated patients:** 2 to 2½ mg, 1 or 2 times daily initially, increasing as needed and tolerated. (See Precautions.) **Children:** 1 to 2½ mg t.i.d. or q.i.d. initially, increasing as needed and tolerated (not for use under 6 months).

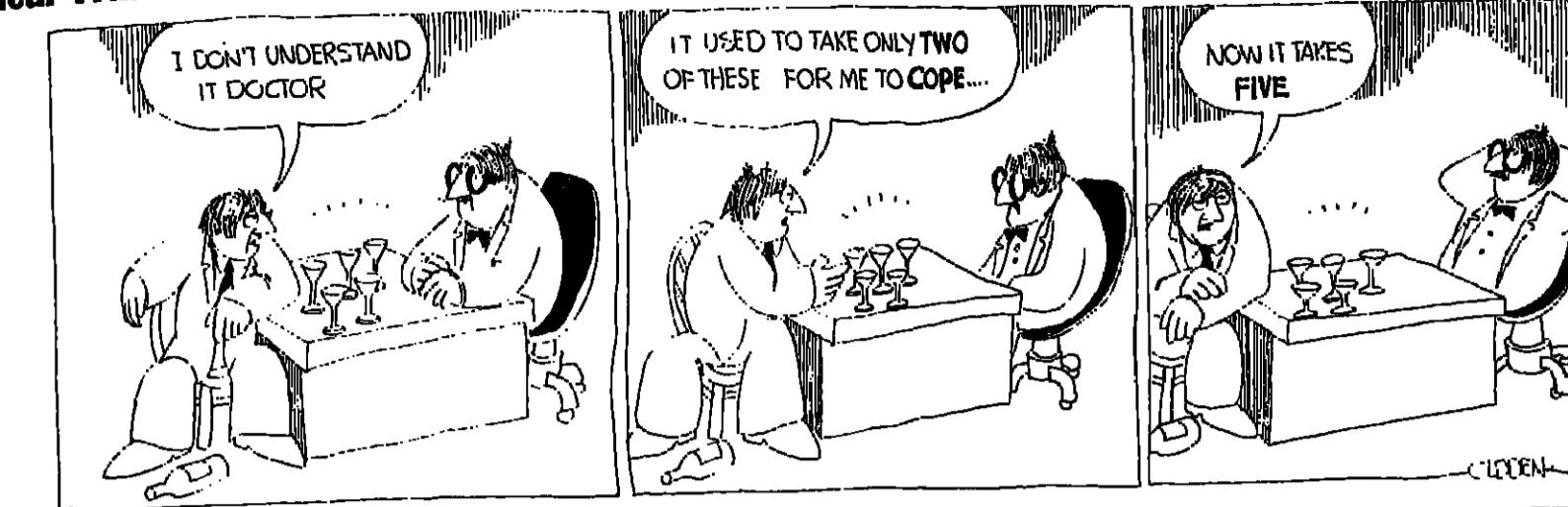
Supplied: Valium® (diazepam) Tablets, 2 mg, 5 mg and 10 mg—bottles of 100 and 500; Tel-E-Dose® packages of 100, available in trays of 4 reverse-numbered boxes of 25, and in boxes containing 10 strips of 10; Prescription Paks of 50, available singly and in trays of 10.

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Nutley, New Jersey 07110

Wednesday, April 16, 1975

MEDICAL TRIBUNE

Clinical Trials



by G.

TRIBUNE SPORTS REPORT

Hang Gliding Said to Point Up Need for 'Action Priorities'

Medical Tribune Report

SAN FRANCISCO—Dr. Arthur E. Ellison of Williamstown, Mass., cited the fast-growing sport of hang gliding as an example of the need to establish "action priorities" in athletic medicine through coordination of research efforts.

He told a meeting of the American Orthopaedic Society for Sports Medicine here that participants in this dangerous pastime have increased from 200 to 11,000 since 1972, with gliding kites now being sold at a rate of about 1,000 a month.

A Death a Month in California

While the exact injury rate is not known, he said, Rancho Los Amigos in Los Angeles has six paraplegic patients who are victims of hang gliding accidents, and California alone averages one fatality a month from this sport.

the terrain, pilot error, and kite failure.

A thorough survey, he said, might suggest that a special action program is required, including: modification of equipment to provide such safety devices as a parachute or an ejection suit; special padding, helmets, gloves, or boots; elimination of flying over dangerous terrain; licensing; a ban on unsound kites; or, if the toll is found to be too high, outlawing of hang gliding altogether.



IMMATERIA MEDICA

Minnesota Medicine's Mascot

The new editor-in-chief of *Minnesota Medicine*, Dr. Richard L. Reeves, has introduced a mascot into his columns. Why? "Because I have one in mind, that's why," says Editor Reeves. "His name is minny."

That brought us up short. Unless, we figured, for *Minnesota*. Editor Reeves says minny is "a literary cockroach who composes free verse by hurling himself head downward against the typewriter keys . . ."

Like Don Marquis' archibald, of *archibald and mehitabel* fame, from whom minny is descended, he can't manage capital letters or punctuation on the typewriter. "minny is bold, disrespectful, fun-loving, contemptuous of detail, and hungry for the literary life," says Editor Reeves, who in his March issue published minny's first poem:

mr minnesota medicine editor
i accept the position
because mascots bring luck
and you will need plenty

Long live minny the mascot of *Minnesota Medicine!* Who knows? This mascot business may be as contagious as measles. We could have ginn for *Virginia Med. M.*, slo for *J. Florida M.A.*, pa for *Pennsylvania Med.*, tex for *Texas M.*, mo for *Missouri Med.*, and missy for *J. Mississippi Med. Ass.*

But now that they are teaching chimps to talk and typewrite, nobody says all mascots have to be cockroaches. In fact, we know some who are just cute nurses.

Calif. Acupuncture Unit With Few MDs Likely

Continued from page 9
puncture which is lobbying to change the Moscone bill.

"There is room for traditional acupuncturists," Dr. Wong said in an interview with MEDICAL TRIBUNE, "but they should be required to show expertise in basic science. By the same token, we also think that M.D.s should not be given carte blanche, but ought to be required to take 100 to 150 hours of acupuncture training, as they must do now in New York."

Alternative Makeup Proposed

"As for the makeup of the Advisory Board, our alternative suggestion is a 10-member Board with the following distribution: one member from the State Board of Medical Examiners; four physician-acupuncturists; one non-medical, academic, research-oriented Ph.D. with at least five years experience with acupuncture; and three traditional acupuncturists trained in Japan, China, or Korea; with at least ten years experience, and demonstrated knowledge of western concepts of anatomy, physiology, etc."

"Our main motive," he added, "is to see that the public is fully protected,

and acupuncture doesn't go 'down the pipes' as quackery."

Sources in Gov. Brown's office told MEDICAL TRIBUNE that he is waiting to study the final version of the Moscone bill before deciding whether to sign it; they said the Assembly often amends or adds to bills received from the Senate.

Neighboring Nevada, in 1973, was the first state to legalize the practice of acupuncture by non-physicians without medical supervision. In the rest of the country, there is a patchwork of regulations, often stipulating that acupunc-

Gonorrhea in Women Declared to Be Often Symptomatic

Medical Tribune World Service

GENEVA—Gonorrhea in women cannot be regarded as commonly nonsymptomatic, a United States physician stated here at a World Health Organization-sponsored meeting on health education in the control of sexually transmitted diseases.

Estimates that up to 60 per cent of infected women, and 10-20 per cent of men, are without symptoms, are largely based on the experience of physicians working in VD clinics, said Dr. King K. Holmes, of University of Washington, Seattle.

"About 80 per cent of women seen in the University of Washington specialty clinics and emergency room have

no symptoms," Dr. Holmes said.

"As manifestations in women that are suggestive of, or compatible with, gon-

orrhea, he cited lower abdominal pain,

abnormal vaginal discharge, dysuria, and urinary frequency, rectal symptoms, joint pains, and skin lesions, and probably abnormal menstrual bleeding also.

While, currently, 10 to 20 per cent

of male patients at VD clinics have no

symptoms, this figure also bears no re-

lationship to the true proportion of

new cases of this kind, Dr. Holmes as-

serted.

"In an unpublished cohort study, we

have found this proportion to be only

3 per cent," he reported.